REMARKS

Claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-127, 129-130, 132-133, 135-136, 138-139 and 185-222 are currently pending. Applicants have canceled claims 52, 79, 99, 117, 196, 202, 206 and 210. Applicants have amended claims 2-4, 129, 132, 138, 215, 217 and 221.

I. 35 U.S.C. § 120

The Examiner again alleges that the subject matter of claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-127, 129-130, 132-133, 135-136 and 138-139 is not disclosed in the parent applications. Applicants respectfully traverse the Examiner's assessment of the effective filing date under §120. In the September 7, 2004 response applicants, as requested, cited those portions of the specifications of the parent applications which provide support for the subject matter of the pending claims. Applicants note that the Examiner has not provided any specific reason, in either the earlier office action dated March 4, 2004 or the present office action, as to why the pending claims are allegedly not supported by the parent applications. Accordingly, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. §120 objection.

II. 37 C.F.R. §1.111(b)

The Examiner alleges that applicants' prior arguments fail to comply with 37 C.F.R. 1.111(b) amounting to a general allegation that the claims define a patentable invention. Applicants respectfully traverse the Examiner's §1.111(b) argument.

Applicants note that in their prior response they clearly laid out examples of how the language of the claims patentably distinguishes from the cited references. Applicants pointed out specific distinctions believed to render the claims patentable over the applied references. For example, applicants maintained that neither Zhang nor Patierno discloses a composition

comprising recombinant human uteroglobin in an amount sufficient to inhibit LPS-dependent inflammatory processes, to decrease TNF-alpha concentrations, to regulate the nitric oxide pathway, or to regulate vascular permeability and a pharmaceutically acceptable carrier or diluent. Applicants also maintain that neither Zhang nor Patierno discloses a composition comprising recombinant human uteroglobin, alone, or with fibronectin or a fragment derived from fibronectin, in amounts sufficient to suppress proliferation of CD71-positive cells, to suppress activation of CD71-positive cells, to enhance proliferation of CD11b-positive cells, to enhance activation of CD11b-positive cells, to suppress migration of vascular endothelial cells, to inhibit angiogenesis, or to inhibit extracellular matrix invasion by vascular endothelial cell. Thus applicants' response meets the criteria set out in 37 C.F.R. §1.111 and therefore is a *bona fide* attempt to advance the application proceeding to final action.

III. 35 U.S.C. §102

The Examiner has rejected claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-27, 129-130, 132-133, 135-136 and 138-139 have been rejected as anticipated under 35 U.S.C. §102(a or b) by Zhang, as evidenced by Pilon and Cummins. The Examiner has also rejected, as anticipated, claims 185-222, relying upon Singh and the rejection of record.

Claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-27 and 135-136 have been rejected as anticipated under 35 U.S.C. §102(e) by Patierno. The Examiner has also rejected claims 185-196, 199-214, 219 and 220, relying upon Singh and the rejection of record.

Applicants respectfully traverse the Examiner's §102 (a or b) and §102(e) rejections. Applicants maintain that presently pending claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-27, 129-130, 132-133, 135-136, 138-139 and 185-222 are not anticipated by Zhang. Furthermore, applicants

respectfully maintain that claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-27, 135-136, 185-196, 199-214, 219 and 220 are not anticipated by Patierno.

Well established Federal Circuit precedent confirms that in order establish anticipation by a reference, that reference must describe each and every limitation of the claim. Applicant respectfully submits that the cited references do not describe each and every limitation of the respective rejected claims.

Singh is relied upon by the Examiner to show that Zhang and Patierno disclose a composition comprising human UG consisting essentially of SEQ ID NO: 1. While Singh, which applicants maintain is not prior art, does describe a sequence for human uteroglobin, Zhang merely describes observations concerning uteroglobin in uteroglobin knockout mice. Zhang does not describe the sequence of SEQ ID NO: 1. Thus, Zhang fails to describe all of the limitations of the pending claims. Furthermore, while Patierno purports to describe a human uterglobin, it does not describe the sequence of SEQ ID NO: 1. Absent any description of the sequence of Patierno's human uteroglobin, it is improper for the Examiner to take the position that Patierno's human uteroglobin is of the same sequence as SEQ ID NO: 1. Thus, while Patierno may generally describe a human uteroglobin, it fails to disclose all of the limitations of the pending claims.

Furthermore, Zhang merely describes observations of renal disease in mice with disrupted mouse uteroglobin genes. In Zhang, the mice with disrupted mouse uteroglobin genes were injected with hFn and uteroglobin, showing a lowered detection of hFn (human fibronectin) in the glomeruli of the mice as opposed to the same mice injected with hFn alone. Thus Zhang merely describes the possibility of preventing deposition of Fn (Fibronectin) in the glomeruli of mice. Furthermore, Patierno merely describes methods and compositions, for example human uteroglobin, which allegedly prevent or inhibit metastases of cancers by inhibiting arachidonic

acid release by cancer cells and by inhibition of PLA2 activity. Patierno merely describes the *in vitro* effect of uteroglobin on invasiveness tumor cell lines and on the release of arachidonic acid by tumor cell lines. Thus Patierno generally describes the effect of uteroglobin on tumor cell invasiveness and arachidonic acid release.

Reference is made to the text of the claims in the "listing of claims" found in this Response. Therefore, applicants respectfully submit that the cited references do not describe each and every limitation of the respective rejected claims for the above reasons and for the following reasons:

Claim 6

With regard to claim 6, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to inhibit LPS-dependent inflammatory processes in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to inhibit LPS-dependent inflammatory processes in a patient.

Claim 13

In reference to claim 13, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to decrease TNF-alpha concentrations and a pharmaceutically acceptable carrier or diluent. For example, neither Zhang nor Patierno disclose, teach or suggest an amount of recombinant human uteroglobin sufficient to decrease TNF-alpha concentrations.

Claim 23

With regard to claim 23, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to regulate the nitric oxide pathway of a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either

Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to regulate the nitric oxide pathway of a patient.

Claim 31

Regarding claim 31, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to regulate vascular permeability of a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to regulate vascular permeability of a patient.

Claim 42

With regard to claim 42, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to suppress proliferation of CD71 positive cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress proliferation of CD71 positive cells in a patient.

Claim 51

Regarding claim 51, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to suppress proliferation of CD71 positive cells in vitro. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress proliferation of CD71 positive cells in vitro.

Claim 60

In reference to claim 60, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to suppress proliferation of CD71 positive cells in vitro. For example, nowhere in either Zhang or Patierno is there any disclosure,

teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress proliferation of CD71 positive cells in vitro.

Claim 69

With regard to claim 69, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to suppress activation of CD71 positive cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress activation of CD71 positive cells in a patient.

Claim 78

Regarding claim 78, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to suppress activation of CD71 positive cells in vitro. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress activation of CD71 positive cells in vitro.

Claim 89

With regard to claim 89, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to enhance proliferation of CD11b-positive cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to enhance proliferation of CD11b-positive cells in a patient.

Claim 98

In reference to claim 98, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to enhance proliferation of CD11b-

positive cells in vitro. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to enhance proliferation of CD11b-positive cells in vitro.

Claim 107

Regarding claim 107, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to enhance activation of CD11b-positive cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to enhance activation of CD11b-positive cells in a patient.

Claim 116

In reference to claim 116, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to enhance activation of CD11b-positive cells in vitro. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to enhance activation of CD11b-positive cells in vitro.

Claim 123

With regard to claim 123, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to suppress migration of vascular endothelial cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress migration of vascular endothelial cells in a patient.

Claim 126

In reference to claim 126, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to inhibit angiogenesis in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to inhibit angiogenesis in a patient.

Claim 129

Regarding claim 129, Zhang fails to disclose, teach or suggest recombinant human uteroglobin and fibronectin, or a fragment derived from fibronectin, in amounts sufficient to suppress migration of vascular endothelial cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in Zhang is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin and fibronectin, or a fragment derived from fibronectin, in amounts sufficient to suppress migration of vascular endothelial cells in a patient.

Claim 132

Regarding claim 129, Zhang fails to disclose, teach or suggest recombinant human uteroglobin and fibronectin, or a fragment derived from fibronectin, in amounts sufficient to inhibit angiogenesis in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in Zhang is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin and fibronectin, or a fragment derived from fibronectin, in amounts sufficient to inhibit angiogenesis in a patient.

Claim 135

In reference to claim 135, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin in an amount sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or

suggestion of an amount of recombinant human uteroglobin sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient.

Claim 138

Regarding claim 138, Zhang fails to disclose, teach or suggest recombinant human uteroglobin and fibronectin, or a fragment derived from fibronectin, in amounts sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in Zhang is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin and fibronectin, or a fragment derived from fibronectin, sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient.

Claim 185

In reference to claim 135, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to inhibit LPS-dependent inflammatory processes in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to inhibit LPS-dependent inflammatory processes in a patient.

Claim 187

Regarding claim 138, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to decrease TNF-alpha concentrations and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to decrease TNF-alpha concentrations.

Claim 189

Regarding claim 107, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 an amount sufficient to regulate the nitric oxide pathway of a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to regulate the nitric oxide pathway of a patient.

Claim 191

In reference to claim 191, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 an amount sufficient to regulate vascular permeability of a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to regulate vascular permeability of a patient.

Claim 193

With respect to claim 193, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 an amount sufficient to suppress proliferation of CD71 positive cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress proliferation of CD71 positive cells in a patient.

Claim 195

Referring to claim 195, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to suppress proliferation of CD71 positive cells in vitro. For example, nowhere in either Zhang

or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress proliferation of CD71 positive cells in a patient.

Claim 197

Regarding claim 197, Zhang fails to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to suppress proliferation of CD71 positive cells in vitro. For example, nowhere in Zhang is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin and fibronectin, each present in an amount sufficient to suppress proliferation of CD71 positive cells in a patient.

Claim 199

With respect to claim 193, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to suppress activation of CD71 positive cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress activation of CD71 positive cells in a patient.

Claim 201

Regarding claim 201, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to suppress activation of CD71 positive cells in vitro. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress activation of CD71 positive cells in vitro.

Claim 203

With respect to claim 203, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount

sufficient to sufficient to enhance proliferation of CD11b-positive cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to enhance proliferation of CD11b-positive cells in a patient.

Claim 205

Regarding claim 205, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to enhance proliferation of CD11b-positive cells in vitro. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to enhance proliferation of CD11b-positive cells in vitro.

Claim 207

With respect to claim 207, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to enhance activation of CD11b-positive cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to enhance activation of CD11b-positive cells in a patient.

Claim 209

In reference to claim 209, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to enhance activation of CD11b-positive cells in vitro. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to enhance activation of CD11b-positive cells in vitro.

Claim 211

Regarding claim 211, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to suppress migration of vascular endothelial cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to suppress migration of vascular endothelial cells in a patient.

Claim 213

In reference to claim 213, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to inhibit angiogenesis in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to inhibit angiogenesis in a patient.

Claim 215

With respect to claim 215, Zhang fails to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 and fibronectin, or a fragment derived from fibronectin, in amounts sufficient to suppress migration of vascular endothelial cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in Zhang is there any disclosure, teaching or suggestion of amounts of recombinant human uteroglobin and fibronectin, or a fragment derived from fibronectin, sufficient to suppress migration of vascular endothelial cells in a patient.

Claim 217

Regarding 217, Zhang fails to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 and fibronectin or a fragment derived from fibronectin, in amounts sufficient to inhibit angiogenesis in a patient, and a pharmaceutically

acceptable carrier or diluent. For example, nowhere in Zhang is there any disclosure, teaching or suggestion of amounts of recombinant human uteroglobin and fibronectin or a fragment derived from fibronectin, sufficient to inhibit angiogenesis in a patient.

Claim 219

Referring to claim 219, both Zhang and Patierno fail to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an amount sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in either Zhang or Patierno is there any disclosure, teaching or suggestion of an amount of recombinant human uteroglobin sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient.

Claim 221

With respect to claim 221, Zhang fails to disclose, teach or suggest recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 and fibronectin or a fragment derived from fibronectin in amounts sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient, and a pharmaceutically acceptable carrier or diluent. For example, nowhere in Zhang is there any disclosure, teaching or suggestion of amounts of recombinant human uteroglobin and fibronectin or a fragment derived from fibronectin, sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient.

Dependent Claims

Regarding dependent claims 7, 14, 24, 32, 43, 52, 61, 70, 79, 90, 99, 108, 117, 124, 127, 130, 133, 136, 139, 186, 188, 190, 192, 194, 196, 198, 200, 202, 204, 206, 208, 210, 212, 214, 216, 218, 220 and 222, which the Examiner argues encompass "essentially any and/or all conceivable amounts because the limitation ['said amount ... 10ng/kg ... of body mass'] encompasses any and/or all conceivable body masses," applicants respectfully maintain that way

in which dosage amounts are calculated for administration to patients prevent any such encompassing. For example, a 100kg patient would receive between 1,000 ng – 2500mg (i.e. 10ng/kg body mass x 100kg body mass = 1,000ng and 25mg/kg body mass x 100kg body mass =2,500 mg). Applicants also note that it is customary to describe dosages in terms of grams of composition per kg of patient weight.

35 U.S.C. § 103

The Examiner has rejected claims 129, 130, 132, 133, 138 and 139 as obvious over Zhang, as evidenced by Pilon and Cummins. The Examiner has also rejected, as obvious, claims 215-218, 221 and 222 relying upon Singh and the rejection of record.

Applicants respectfully traverse the Examiner's §103 rejection. Applicants maintain that presently pending claims 129, 130, 132, 133, 138, 139, 215-218, 221 and 222 are not rendered obvious by Zhang as evidenced by Pilon, Cummins and/or Singh, either alone or in combination.

In order to establish a *prima facie* case of obviousness the cited references must disclose, teach or suggest all of the claim elements, there must be a reasonable expectation of success in the combination and there must be some suggestion or motivation to modify the reference or combine reference teachings. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); MPEP §§ 2142 and 2143. Applicant respectfully submits that a *prima facie* case of obviousness cannot be established since none of these conditions have been met.

Reference is made to the text of the claims in the "listing of claims" found in this Response.

Claim 129

With respect to claim 129, the Zhang reference, alone or in combination, does not disclose, teach or suggest, *inter alia*, an amount of recombinant human uteroglobin and

fibronectin, or a fragment derived from fibronectin, in amounts sufficient to suppress migration of vascular endothelial cells in a patient.

Claim 132

With respect to claim 132, the Zhang reference, alone or in combination, does not disclose, teach or suggest, *inter alia*, an amount of recombinant human uteroglobin and fibronectin, or a fragment derived from fibronectin, in amounts sufficient to inhibit angiogenesis in a patient.

Claim 138

With respect to claim 138, the Zhang reference, alone or in combination, does not disclose, teach or suggest, *inter alia*, an amount of recombinant human uteroglobin and fibronectin, or a fragment derived from fibronectin, sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient.

Claim 215

With respect to claim 215, the Zhang reference, alone or in combination, does not disclose, teach or suggest, *inter alia*, amounts of recombinant human uteroglobin and fibronectin or a fragment derived from fibronectin, sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient.

Claim 217

With respect to claim 217, the Zhang reference, alone or in combination, does not disclose, teach or suggest, *inter alia*, amounts of recombinant human uteroglobin and fibronectin or a fragment derived from fibronectin, sufficient to inhibit angiogenesis in a patient.

Claim 221

With respect to claim 221, the Zhang reference, alone or in combination, does not disclose, teach or suggest, *inter alia*, amounts of recombinant human uteroglobin and fibronectin,

or a fragment derived from fibronectin, sufficient to suppress migration of vascular endothelial cells in a patient

Dependent claims

With respect to dependent claims 130, 133, 139, 216, 218 and 222, applicants refer to their discussion above concerning the Examiner's interpretation of "10ng/kg ... of body mass."

35 U.S.C. §112 second par.

The Examiner has rejected claims 129, 130, 132, 133, 138, 139, 215-218, 221 and 222 as indefinite over the recitation of "derived from." Applicants respectfully traverse the Examiner's §112 second par. rejection for the reasons stated in their response dated September 7, 2004. However, solely to speed prosecution and place the claims in better condition for appeal, applicants have hereinabove amended claims 129, 132, 138, 215, 217 and 221 to recite "fragment of fibronectin." Applicants respectfully maintain that the Examiner's §112 second par. rejection is thus rendered moot.

The Examiner has also rejected claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-27, 129-130, 132-133, 135-136 and 138-139 as indefinite over the recitation of "recombinant human uteroglobin." Applicants respectfully traverse the Examiner's §112 second par. rejection for the reasons stated in their response dated September 7, 2004. Applicants additionally point out that the section of the specification cited by applicants as defining the term "recombinant human uteroglobin" bears a heading entitled "definitions." (Spec. at p. 17). Thus applicants respectfully assert that the Examiner's statement that the definition at page 17 is "merely exemplary and not intended to limit the definition of recombinant human uteroglobin" is without basis. Furthermore, the Examiner has not pointed out why the definition in the specification is "merely exemplary."

Based on the foregoing, applicants respectfully request that the Examiner withdraw the §112 rejections.

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For at least the reasons set forth above, the pending claims are urged as being in condition for allowance or at least in better condition for appeal. Prompt allowance is therefore respectfully requested. If any issues remain outstanding, Applicant respectfully requests the opportunity to discuss same in a telephone interview with the Examiner.

No additional fees, other than the fee for a three month extension of time and a notice of appeal, are believed to be necessary in connection with the filing of this Amendment. However, if any additional fees are required, the Commissioner is hereby authorized to charge such fee(s) to Deposit Account No. 05-0765.

Respectfully submitted,

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